

AMENDMENTS TO THE SPECIFICATION:

Please amend page 1, paragraph 3, to read as follows:

FIELD OF THE INVENTION

The present invention relates generally to [surgical] medical instruments and, more particularly, to devices for [surgery performed by] use in endoscopic [procedure] surgery and the like.

Please amend page 1, paragraph 4, to read as follows:

BACKGROUND OF THE INVENTION

[In e]Endoscopic surgery, [for instance,] i.e., minimally invasive access to a cavity of [the] a patient's body, such as the abdominal cavity, is typically performed through the use of miniaturized optical and surgical instruments. In the case of the laparoscopic surgery, which involves the peritoneal cavity, th[is] e cavity is essentially virtual in the mind of the surgeon and cannot be explored by optical instruments. In order to give [it] the cavity more substance, its walls [is] are raised by insufflating gas, generally CO₂, to form a gas chamber, known as pneumoperitoneum. Access to the pneumoperitoneal chamber is accomplished using trocars or small incisions that are fit[ted] with a valve, so that communication between the interior and exterior of the abdomen [takes place] occurs without [a] significant variation [of the] in actual [gas] pressure of the gas. [The

s]Surgical instruments [are] may then be inserted through the trocars and the optics connected externally to a TV camera and, in turn, to a monitor, thereby forming a take and image transmission system.

Please amend page 2, paragraph 1, to read as follows:

Even if the pressure exerted on the patient's organs by the pneumoperitoneum facilitates spontaneous haemostasis of the countless capillaries [which] that are lesioned, it is [however essential] considered necessary that perfect haemostasis be [performed straightway,] achieved throughout. O[o]therwise, visibility [is] inside the cavity may be reduced [until it is] to such an extent that it may be impossible, [and in any case] or at least [un]inadvisable, to continue the operation by [the] laparoscopic procedure without [the necessary] sacrificing the patient's safety. Normally, [in] during this type of operation, [the] outflowing blood and liquids are aspirated to keep the surgical site clean and ensure adequate instrumental visibility. [However] Unfortunately, [implementation of] aspiration is not [wholly] only inefficient to implement, but also several seconds are required to commence the aspiration process and can only be put into use after a few moments, which delay is unfortunately often decisive. As an alternative, [T]the use of absorbent plugs inserted through a trocar at [in] the surgical site [by means of] using a forceps [through a trocar is equally] has been found similarly inefficient.

Please amend page 2, paragraph 2, to read as follows:

In one arrangement, an instrument is provided for insertion of a haemostatic plug into the abdominal cavity during a laparoscopic procedure. Such instrument [is formed by] includes a tubular element for receiving a plug of haemostatic material and a sliding plunger for applying the plug directly where bleeding has occurred.

Please amend from after paragraph 2 on page 2 to before the first full paragraph on page 3 to read as follows:

[The] One disadvantage of these arrangements ~~device described above, as well as~~ in the case of the insertion of a plug by means of a forceps through a trocar, ~~lies in the~~ fact is that [the] recovery of the plug [by means of] using a forceps [may] can be laborious and even dangerous, especially [in the case of a] during laparoscopic [surgical operation] surgery for the removal of a tumo[u]r. [In this case] During this procedure, the dissemination of cells, including those that may be cancerous [cells], [due to the] caused by partial squeezing of the plug [during its passage] as it passes through the trocar, may take place at a site far from that where the tumo[u]r developed and [may therefore] can thus give rise to [very] serious remote neoplastic dissemination which is difficult to treat. Because the plug becomes soaked with blood or other bodily fluids, [T]here is also [a definite] considerable risk [of] that the surgeon may either be unable to find and remove the plug or simply "forget[ting]" the plug after it has been introduced into [the] a patient's body cavity ~~or in any case it may be difficult to find it again for~~

~~removal when it is soaked with blood or other bodily fluids. [This] Such “oversights” [is~~
~~a frequent] often result in [source of] medical and legal disputes. While these disputes~~
~~are generally [and, albeit] less frequent in laparoscopic surgery than in [compared to]~~
~~“open” surgery, constitutes in any case a not negligible the risk is considered significant.~~

Please amend page 3, first fully paragraph, to read as follows:

OBJECTS AND SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a device for removing organic fluids from a body cavity of a patient during a medical procedure so as to overcome inefficiencies and delays attendant aspiration of such fluids, avoid the inefficient, labori-ous and hazardous nature of inserting absorbent plugs using a forceps, and eliminate the risk of oversight associated with removing [such] the plugs during the procedure.

Please amend page 3, second full paragraph, to read as follows:

Another [particular] object of the present invention is to provide a device for [the] inserti[o]ng [of] an absorbing plug into a[n] patient’s abdominal cavity during [a] laparoscopic surg[ical]ery, [operation] which device also allows the plug to be safely and easily locat[i]oned at the surgical site [of the plug], [thus] thereby facilitating its recovery after use and [in this way] avoiding the risk of its lo[osing]ss at [the plug in] the surgical

site[, and leaving it] (and of being left in the patient's body[, and also]) as well as avoiding possible cell[s] dissemination [in areas far from] remotely to the [surgical] site.

Please amend page 3, third full paragraph, to read as follows:

A[nother] further object of the present invention is to provide a[n] haemostatic plug [which can easily] that may be easily retrieved and recovered after use.

Please amend from after the third full paragraph on page 3 to before the first full paragraph on page 4, to read as follows:

~~These objects are achieved with the~~ According to one aspect of the present invention, a device is provided for [the] remov[al]ing [of] organic fluids from a patient's body cavity during [an] endoscopic surgery ~~operation according to the present invention whose feature consists in that it.~~ The device comprises an absorbing plug [and], a tubular body[,] suitable for slidingly housing the plug, and a plunger [which can be engaged] slidingly engageable in[side] the tubular body so as to push the plug outside thereof and place it at the surgical site[, said]. The tubular body and plunger have a distal end and a proximal end. The plug [being] is preferably connected to [plug location means comprising] a radio-opaque [body] plug locator that float[ing]s [on the] relative to internal organs, blood or other liquids present at the surgical site, ~~means for gripping said location means being provided.~~ A[a]t the distal end of the plunger, a handle is provided

for gripping the locator [for] and recovering the plug [and withdrawing it] after use by retracting the plunger inside the tubular body.

Please amend the new paragraph added previously before the first full paragraph on page 4 as follows.

~~Still other objects and advantages of the present invention will become apparent from the following description of the preferred embodiments.~~

Please amend page 4, second full paragraph, to read as follows:

FIG. 1 is a partial perspective view of a device, according to one aspect of the present invention[.];

Please amend page 4, fifth full paragraph, to read as follows:

FIGS. 4a - 4c illustrate steps of a method for recovery of the plug using the device shown in FIG. 1, according to one aspect of the present invention.

Please amend page 4, sixth full paragraph, to read as follows:

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings and, more particularly, to FIGS. 1 [and 2] - 4c, there is shown generally a specific, illustrative, surgical device, in accordance with various aspects of the present invention. According to one embodiment, shown generally in FIG. 1, the device comprises a relatively rigid tubular sheath with open distal and proximal ends 1a and 1b, respectively. A proximal portion of the sheath is engaged firmly with a hub 2 having a handle such as in the form of two diametrically oppos[s]ing annular grips 3a, 3b generally coplanar to the sheath.

Please amend from after the sixth full paragraph on page 4 to before the first full paragraph on page 5 to read as follows:

A stem 4 is slidably inserted in [the] tubular sheath 1 [whose], the distal end [4a] of which has an eyelet configuration [made] that, [in the present] according to one embodiment of the present invention, is constructed of [with] a flexible thin plate 5 bent in [two in such a way] half so as to form a loop with its ends connected to [the] distal end 4a of the stem [4] via a transverse peg 6 ([Figure] as best seen in FIG. 3). Advantageously, in one embodiment, [the thin] plate 5 may be a strip of rectangular section and may be [made] constructed of a selected harmonic or nickel-titanium steel[, in such a way as] to suitably exhibit sufficient flexural rigidity. [The p]Proximal end 4b of [the] stem 4 [ends with] mounts an annular grip 7 which, in the present embodiment, is

connected to the stem by a steel peg[,] (not shown[,]) [to the stem 4] and co-planar there[to]with.

Please amend page 5, first full paragraph, to read as follows:

The tubular sheath [1] and the stem [4] are preferably made of a selected metallic or [of a plastic] polymeric material suitable for surgical use, for example, polyethylene, [Teflon] TEFLON and the like. [The a]Annular grips 3a, b and 7 are [made] desirably constructed of a similar material. Circumferential grooves 11 are advantageously provid[ing]ed along [the] stem 4 for housing O-rings[,] (not shown)[,] suitable for facilitating sliding along the internal lubricated surface of [the] tubular sheath 1.

Please amend from after the first full paragraph on page 5 to before the first full paragraph on page 6 to read as follows:

The device, according to the present invention, preferably also comprises an absorbent plug 8 [which] ha[s]ving an elongated shape and, [in] more particularly, a [it is] substantially pear-shape[d], [its] such shape being suitable for [allowing it to be] enabling its insert[ed]ion in the tubular sheath [1]. [The p]Plug 8 is connected by a wire 9 to a ball 10 [with] (i) having a [lower] specific weight generally lower than that of blood[, and therefore] such that it float[ing]s [in relation] relative thereto, and (ii) being generally radio-opaque so as to be visible to X rays. The ball [10] should preferably be colo[u]red so as to be visually identifiable within the surgical field and [must] have a

surface finish [such as to] suitable for allowing blood to slid[ing]e [of blood] over its surface. The plug [8] can be made of any material suitable for haemostasis and for the absorption of blood and any other liquid which may be present in the surgical field. [Advantageously it] Beneficially, the plug may be [made] constructed of polyvinyl alcohol (PVA) as in [the] a product available under the commercial names [Meracel®] MERACEL, [or Ivalon®] IVALON or other equivalent products.

Please amend page 6, first full paragraph, to read as follows:

[The] Additionally, [w] Wire 9 is made of a biocompatible material, [for example] such as suture thread, [with] having a diameter of about 0.5 mm and length [of] generally within a range of 8[-] cm and 10 cm.

Please amend page 6, second full paragraph, to read as follows:

The dimensions of [the] ball 10 are such as to allow its insertion into [the] tubular sheath 1 and, in turn, determine the dimensions of the loop so formed at [the] distal end 4a of [the] stem 4, which dimensions must necessarily [has to] be slightly larger than that of [the] body 10. [Said] The ball must also be radio-opaque and white in colo[u]r (or yellow, or [in any case] another light colo[u]r) so as to be easily identified at the surgical site[, and also radio-opaque]. Optionally, a plurality [More than one] of [said] balls may [also] be provided, in addition.

Please amend page 6, third full paragraph, to read as follows:

Desirably, t[T]he length of the stem [4] is greater than or, at most, equal to that of the tubular sheath [1] to ensure that [the] eyelet end 4a of the stem [4] projects fully from the [tubular] sheath [1] when the stem [4] is fully inserted therein [said sheath].

Please amend page 6, fourth full paragraph, to read as follows:

In order to locate [drive] the plug [to] at the surgical site, ~~the abdominal cavity is reached through a trocar by introducing therein~~ [the] tubular sheath 1 of the insertion[g] device , where the plug had been placed previously, is introduced into the patient's abdominal cavity through a trocar [wherein a plug 8 has previously been placed]. By sliding the stem [4], which [acts as] operates like a plunger, the plug [8] is pushed outside of the tubular sheath [1] and [positioned] located by the surgeon [in] at the place of use.

Please amend from after the fourth full paragraph on page 6 to before the first full paragraph on page 7 to read as follows:

Once the plug [8] has [performed] served its function, it [has to] must be recovered and [taken outside of] removed from the abdominal cavity. [For this purpose] To this end, as shown in [Figures] FIGS. 4a, b and c, initially [the] ball 10 is identified visually [and the]. E[e]yelet end 4a of the stem [4] is then moved towards [it, to get the ball to] the ball such that it passes suitably through the loop [so as to] and hooks [the]

wire 9 of the plug [8]. Next, through light hand movements of the surgeon, [T]he loop is [then made] caused to slide along the wire [with light hand movements and], pulling the stem [4] [is pulled] backwards, generally in the direction of arrow F in [Figure] FIG. 4c, until the plug has returned [fully] to a position completely inside the tubular sheath [1,]. Thereafter, [which] the device is disengaged from the trocar.

Please amend page 7, first full paragraph, to read as follows:

~~The advantage obtained with the use of the device according to~~ Overall, the present invention is especially advantageous [consists] in that [the operation of] recovery of the plug[,] and [in], more particularly, its reinsertion in [the] tubular sheath 1 after use, is performed directly at the surgical site, so that [the inevitable] partial squeezing of the plug, as inevitably occurs during use, is not a source of remote contamination[, particularly]. Contamination is particularly dangerous during removal of a tumor, namely, when [in the presence of] tumoral cells [due to] are present, given the possibility of neoplastic dissemination [with] and the risk of [the] formation of metastasis. More specifically, [the] partial squeezing of the plug, ~~as in the surgical site gives rise, in the a~~ worst [hypothesis] case scenario, is tantamount [to a] microscopically to incomplete removal of the tumo[u]r[, moreover]. ~~If inevitably,~~ with or without the plug, [which will] while this may still give rise to the possibly [to] of a [local] relapse of the disease locally, [always] it is prefer[able]red when compared to the severity of remote metastasis.

Please amend page 7, second full paragraph, to read as follows:

Furthermore, t[T]he loop hooking device [described above] of the present invention is [currently considered preferred due to] highly desirable for its simplicity and effectiveness. It is moreover evident that equivalent hooking devices, which may be suggested to a person skilled in the art on reading this description, are to be considered as coming within the scope of this invention. As those skilled in the art will appreciate, based on a review of this disclosure, other equivalent hooking devices may be utilized within the spirit and scope of the present invention.